K123276

MAR 1 0 2014

SECTION 5: 510(k) Summary

Submitter

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Date Prepared

September, 2012, corrected for additional information in November 2013

Device Information

Trade name: MM-SEAL
Common name: Root canal sealer
Classification Name: Root Canal Filling Resin
Review Panel: Dental
Product Code: KIF
Device Class: II

Devices to which substantial equivalence is claimed:

510(k) number	Trade or propriety name	Manufacturer
K042769	ADSEAL	META BIOMED CO,LTD

Indications for Use:

The MM-SEAL is a root canal sealer packaged in a dual syringe used for filling of root canals with gutta percha points for endodontic treatments.
MM-SEAL is intended for use by qualified healthcare personnel trained in its use.

Device Description

The MM-SEAL is a biocompatible root canal sealer packaged in a dual syringe used for filling of root canals with gutta percha points for endodontic treatments.

The device consists of two component (dual syringe) which are mixed before the use in the dental canal, onto a mixing plate with a spatula for 15-20 seconds or until the mixture become creamy and homogeneous.

Application: Thoroughly dry canals walls and apply MM-SEAL, avoiding the formation of air bubbles. Do not exceed the apical limit. Dip the tips of dry, disinfected Gutta-percha points in MM-SEAL. Insert one or more points in the root canal and condense the Gutta-percha. MM-SEAL can be used with thermoplasticized gutta-percha or gutta-percha coated obturator techniques.

MM-SEAL should not be used expiry date.

MM-SEAL is intended for use by qualified healthcare personnel trained in it use.

Performance

The performance of MM-SEAL has been evaluated following the standard ISO 6876, Dental root canal sealing materials, the risk analysis has been conducted following ISO 14971 (see appendix 4), the biological evaluation has been done following ISO 10993-1 Biological evaluation of medical devices.

Compararison with the predicate device

The MM-SEAL has the same manufacturer (META BIOMED CO) than its predicate device (ADSEAL K042769) and the same intended use, the same chemical composition, the same physical properties, the same manufacturing process, the same method of application, a very similar user manal and a similar packaging as its predicate device ADSEAL (META BIOMED CO). The detailed comparison is done is section 12.

Conclusion

The MM-SEAL was compared against its predicate, and was found to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 10, 2014

Micro-Mega Societe Anonyme
Mr. Philippe Conche
Regulatory Affairs Manager
5 – 12 rue du tunnel
25006 Besancon Cedex
FRANCE

Re: K123276
Trade/Device Name: MM-SEAL
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: February 6, 2014
Received: February 10, 2014

Dear Mr. Conche:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith -S

Erin I. Keith, M.S.
Acting Director
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Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: Indications for Use

510(k) Number: K123276

Device Name:
MM-SEAL - Root Canal Sealer

Indications for Use:

The MM-SEAL is a root canal sealer packaged in a dual syringe used for filling of root canals with gutta percha points for endodontic treatments.

MM-SEAL is intended for use by qualified healthcare personnel trained in its use.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner -S
DDS, MA
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